SELF CENTERING ENDODONTIC FILES

FIELD OF THE INVENTION

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The present invention relates to self-centering rotating endodontic files for dental root canal procedures.

BACKGROUND OF THE INVENTION

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When a root canal procedure is being performed, the pulp tissue and bacteria must be removed from the root canal of the tooth. Often the canals are curved, thus necessitating a cleaning file, which can bend as it negotiates further into the canal.

Traditionally, files were hand held instruments having spiral fluting with triangular or square cross sections.

The file was inserted into the canal and moved between the thumb and forefinger in incremental, reciprocating movements.

Later, reciprocating machines, which mimic that hand motion, were used. Now, fully rotational driven hand pieces are used.

Tapered rotating dental endodontic files are used to clean the inside of a root canal in endodontic procedures. Typically these files are tapered fluted bodies, with spiral fluted cutting surfaces providing a working surface for cleaning the conical interior of a root canal.

Also traditionally, the files are twisted or ground before use to create the fluting. Generally, stainless steel files are

twisted and nickel titanium files are ground (while clamped), because nickel titanium is superelastic with corresponding shape memory of the alloy, which makes a permanent twist difficult to achieve.

The nomenclature for sets of files is based upon the geometry of the taper of the fluted files. The tapers are defined by the change in width of the fluted cone defining the file. For example, tapers usually vary in increments of the width in parts of millimeters per each increase in lengthwise length of the file.

For example, an "02" file means that for every lengthwise millimeter change in length the width changes 0.02 millimeter. An "04" file means that for every lengthwise millimeter change in length the width changes 0.04 millimeter. An "06" file means that for every lengthwise millimeter change in length the width changes 0.06 millimeter. An "08" file means that for every lengthwise millimeter change in length the width changes 0.08 millimeter.

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In the past, the files have been made from stainless steel.

Stainless steel files are easy to twist into a fluted configuration and honed to a point. However, the problem with stainless steel is that it lacks shape memory and superelasticity. That is, if bent out of shape, like a paper clip it remains in the bent shape.

More recently, rotary endodontic files are made of nickel titanium, a metal alloy that has shape memory and

superelasticity. However, nickel titanium files are hard to twist like stainless steel, because like a rubber band they tend to return to their original shape, and will "untwist."

Therefore, production of nickel titanium files involves isolating the pre-fluted file in a stationary position, where grinding wheels are applied to the file, such as CNC (computer numerically controlled) ROLLAMATIC machines.

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Moreover, U.S. Patent Nos. 5,984,679 and 6,315,558 B1, both of Farzin-Nia et al, describe a new procedure, in which nickel titanium can now be twisted.

A major problem with mechanically rotated endodontic files is that unless there is a non-cutting surface touching opposite portions of the inside of the canal being routed and cleaned by the rotating file, the file will erratically deviate off center within the canal, sometimes damaging or even perforating through the root canal wall, rendering root canal therapy impossible to achieve and the necessity for extraction of the tooth.

For example, if the diameter of the tapered rotating file is less than the diameter of the portion of the tapered root canal where the working surface of the rotating file is being applied, the file may tend to erratically deflect and cause damage to the root canal wall, possibly permanently damaging the tooth.

Attempts to solve this problem include providing rotating endodontic files with a "radial land" following the fluted cutting edge of the endodontic file.

For example, the convex area following the cutting edge is

known as the "radial land", which is defined as a curved surface portion of a file behind the cutting edge, which extends out radially as far as the cutting edge. Variations of radial lands have the trailing end of the land cut back and recessed, hence they are called recessed radial lands.

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When viewed in crossection, these radial lands define a sector of a circle, i.e. a portion of the cross sectional circumference, which is the "radial land" or a "circumferential land." The "land" is followed by a gap, and then there is provided another cutting surface followed by a trailing radial land.

By contacting the previously cut wall of the root canal, these radial lands keep the rotating file centered while the cutting edges engage the dentin on the inside conical surface of the root canal.

If one does not use radial lands, then there is a possibility that the diameter of the fluted file is less distinct than that of the root canal, which will cause sudden erratic movements of the rotating file bit, possibly damaging a tooth.

Because of the consistent intermittent contact of opposite portions of the inner tapered root canal by the file, the file is "centered" in a proper orientation within the canal.

Among related patents defining radial lands include US

Patent Nos. 6,074,209 and 6,106,296, both of Johnson. Johnson

'209 further attempts to reduce the locking and abrupt movement

of the rotating endodontic file by providing zones of smaller

diameters on a fluted working portion of the file, thereby reducing the total contact surface and hopefully reducing the stalling lock and jerking problems associated with torque.

Among related patents include US Patent No. 4,850,867 and 6,261,099, both of Senia and Wildey. The Senia '867 patent has a non-cutting tip and a non-cutting segment at the opposite end of the tapered fluted working portion, but the non-cutting segment has a smaller diameter than the tapered fluted working portion.

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A cylindrical non-cutting shaft is shown in US Patent

5,762,497 of Heath. It acts solely as a shaft, does not engage
the canal wall and therefore cannot help in self centering the
file. In contrast to the present invention, Heath '497 requires
radial lands for centering the file within the root canal.

However, as noted before, if the diameter of an active cutting region is less than the inner diameter of a root canal being filed by a rotating endodontic file and the non-cutting portion is less than the cutting portion diameter, these files have a tendency to bounce off the inside of the canal and jerk erratically and suddenly sideways, causing trauma and deviating from the path of the root canal itself.

Moreover, US Patent No. 5,947,730 of Kaldestad also describes a cylindrical non-cutting shaft at the proximal, non-tip end of the file above the fluted working portion therein.

Kaldestad '730 also discusses the use of an annular stop in

Figure 3 therein to stop penetration. Furthermore, Kaldestad '730 discusses using a set of three files of sequential taper for

preparation of a root canal.

Unlike the present invention, Kaldestad '730 needs radial lands for self centering a file and does not disclose the use of governor collar to self center a file, and as well the fact that all of the files of Kaldestad '730 have a taper greater than .06 mm for larger apical preparations.

Furthermore, Kaldestad '730 does not disclose use of a particular set of three files including a first file for opening a root canal, a second file for negotiating and cleaning the root canal and a third shaping file that provides the final taper to the root canal.

OBJECTS OF THE INVENTION

It is therefore an object of the present invention to provide a self-centering endodontic file, which does not require the use of trailing radial lands following respective cutting edges.

It is also an object of the present invention to provide a set of files which minimizes the number of files needed by a dentist, wherein the files are sequentially organized depending upon the canal size of the patient.

Other objects which become apparent from the following description of the present invention.

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SUMMARY OF THE INVENTION

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In keeping with these objects and others which may become apparent, the present invention is a tapered self-centering rotating endodontic file having three contact points, including one non cutting tip at the distal end and two contact points at the top above the fluted cutting file. The top portion is in the form of an annular governor collar, such as, for example, a truncated cone or cylinder, which merges into the handle.

The annular governor collar has a limited height, of between about 1.0 mm to 2.0 mm, to allow a space above the cutting portion for accumulation of debris, which would not be possible with a continuous collar extending up to the handle.

The self-centering endodontic dental file is superelastic for curved tapered intra-canal filing, and it does not require the use of a "radially extending" radial land trailing a cutting edge of the file. Hence, the rotating file of the present invention does not allow abrupt transverse movement of file against the inner wall of the canal.

This self-centering feature is accomplished by providing the smooth, non-cutting annular governor portion on the file, away from the fluted cutting edges of the file. The governor is preferably a small, smooth, truncated cone portion or alternatively a smooth cylinder, which is provided on the file above the fluted portion, so that the governor can contact the inner walls of the canal as the cutting edges are cleaning and

shaping internal dentinal walls of the canal.

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Unlike the generally triangular cross section of the fluted portion of the file, the smooth governor portion is circular in cross section.

In certain embodiments for a truncated cone or a cylinder, the axis of the governor portion is parallel to and coextensive with the axis of the tapered fluted portion.

In another embodiment, the truncated conical governor collar or the cylindrical collar may be oriented with an axis, which is not coextensive and parallel with the axis of the fluted portion, so that its axis is tilted, i.e., oriented at an angle off of the major axis of the fluted file.

In addition, the self-centering tapered endodontic file is provided with a smooth non-cutting apex, so that during rotation, the file is self centered by the contact of the governor against the two opposite sides of the inner wall of the tapered root canal and thirdly by the contact of the smooth apex of the file with the converged bottom of the root canal.

The invention also includes a color and numerically coordinated visually ergonomic set of groups of three files each for small, medium and large root canals provided with it.

The reason for minimizing the number of files is because each root canal size needs only sequentially a first file for initially drilling into and opening the root canal, a second file for routing out most of the interior of the tapered root canal and a third file for finishing the shaping and cleaning of the

root canal.

The proximal tops of the files are identified with indicia such as "A", "B" or "C" or "1", "2" or "3", such as, for a first file A for first enlarging the root canal orifice, a second file B for cleaning most of the interior of the tapered root canal and a third file C for finishing the shaping and cleaning of the root canal.

The files are further color coordinated by aligned, slanted bands at the proximal non-cutting cylindrical ends of the files, wherein further the position of the band upon the top, middle or lower portion of the proximal non-cutting cylindrical ends of the file further defines the applicable order of the file to be used with a predetermined determination that the root canal is small, medium or large.

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BRIEF DESCRIPTION OF THE DRAWINGS

The present invention can best be understood in connection with the accompanying drawings. It is noted that the invention is not limited to the precise embodiments shown in drawings, in which:

Fig. 1 is a side elevation view of a prior art endodontic rotary file;

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Fig. 2 is a side elevation view of an endodontic rotary file

of this invention (with the apical distal end tip shown separately for convenience)

- Fig. 3 is a horizontal crossectional sagital view of a non
 cutting governor collar thereof, taken along view arrow lines "22" of Figure 2;
- Fig. 4 is a horizontal crossectional sagital view of an active cutting region thereof, taken along view arrow lines "3-3" of Figure 2;
 - Fig. 5 is a side elevational view of an alternate embodiment of for a rotary endodontic file of this invention (with the apical distal end tip shown separately for convenience);
 - Fig. 6 is a tilted crossectional sagital view of a tilted non-cutting governor collar for the rotary endodontic file shown in Figure 5, taken along view arrow lines "6-6" of Figure 5;

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- Fig. 7 is a horizontal crossectional sagital view of the tilted governor collar of the alternate embodiment shown in Figures 5 and 6, taken along view arrow lines "7-7" of Figure 5;
- Fig. 8 is a partial side crossectional view of a tooth

 25 showing the loose fit of a prior art rotary endodontic file in a root canal thereof;

Fig. 8A is a partial side crossectional view of a tooth showing a tight close fit of a prior art rotary endodontic file, shown working in a root canal;

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- Fig. 9 is a partial side crossectional view of a tooth showing the tight close fit of the rotary endodontic file of this invention, shown working in a root canal;
- Figs. 10A, 10B and 10C are side elevation views of three different variations of shaft designs as used with endodontic files of this invention;
- Fig. 11 is a side elevation detail of an alternate

 15 embodiment of the file shown in Figure 2, wherein the governor is
 a cylindrical section with non-tapered sides;
- Fig. 12 is a side elevation detail of an alternate embodiment of the file shown in Figure 5 wherein the tilted governor is a cylindrical section with non-tapered sides;
 - Fig. 13 is a top plan view of a holder annotated with a diagram showing a coordinated organization of sets of files into sets of files organized in overlapping inverted "Y" configurations for enlarging, cleaning and finishing the cleaning of respective root canals;

Figure 13A is a front elevational view in partial crossection of the area shown in the ellipse "13A" of Figure 13;

Fig. 14 is a side elevational view of a set of three files

for enlarging, cleaning and finishing the cleaning and shaping of respective root canals of a specified size.

DETAILED DESCRIPTION OF THE INVENTION

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Figure 1 shows a prior art rotary endodontic file 101 having handle 102, a short cylindrical non-cutting shank 103 and a tapered active cutting region 104 having a length La (typically 16mm under International Standards Organization (ISO) standards). The combined length of cylindrical non-cutting shank 103 and a tapered active cutting region 104 is shown as length Lt. A cutting or non-cutting tip 105 may also be provided. It is further noted that the diameter Ds is equal to or less than the diameter Dh of active cutting region 104, so that the diameter Dh of the widest portion of active cutting region 104 is not less than Ds.

Therefore, if the diameter D_h of the active cutting region 104 is less than the inner diameter of a tooth canal being filed by rotating endodontic file 101, the rotating endodontic file has a tendency to abruptly engage the side of the canal and move erratically and suddenly sideways, causing trauma to the tooth and deviating from the path of the root canal itself.

Some prior art rotary endodontic files are provided with smooth, non-cutting radial land sections following a fluted cutting surface of active cutting region 104 to reduce the tendency to grab in the side of the canal and move erratically and suddenly sideways. However, providing trailing radial land sections upon a fluted cutting surface is difficult to configure and manufacture, as well as reducing overall efficiency of the file.

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In contrast, the rotary endodontic file 1 of this invention shown in Figure 2 has simplified features to minimize or eliminate this problem of the tendency of rotating endodontic files to overly engage the side of the canal and move erratically and suddenly sideways. To solve this problem, a short non-cutting governor collar 3 has been added atop active region 4 and below shaft 2. The governor collar is a tapered or non-tapered collar with respect to the axis of file. It is called a "governor" since it automatically positions the rotary file 1 in the center of the canal in a fashion analogous to the manner in which an engine governor automatically regulates the speed of an engine. A non-cutting tip 5 is also used.

Use of a governor collar applies to a file length where the length of the working surface, (cutting region) is less than that of a standard file having a cutting region length L_a of less than 16 mm because the governor collar 3 will keep a shorter file centered better.

Furthermore, while shaft 2 of Figure 2 is shown merging with

the governor collar 3, wherein shaft 2 has a diameter less than the diameter of the governor collar 3, it is known that other configurations can be provided, wherein the diameter of the shaft is equal to the diameter of collar 3 (not shown).

Figure 3 shows a smooth circular crossection sagital cut of governor collar 2.

Figure 4 shows a crossection sagital cut of the spiral twisted triangular active cutting region 4.

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Figure 5 shows an alternate embodiment of rotary file 10 of this invention. It differs from that shown in Figure 2 by virtue of using a tapered but tilted non-cutting governor collar 12 between active region 13 and shaft 11. A non-cutting tip 14 is also used here.

Figure 6 is a tilted sagital cut view in crossection perpendicular to the axis of collar 12; it is circular.

Figure 7 is a horizontal sagital cut view in crossection at the junction of shaft 11 and collar 12.

In addition, while shaft 11 is shown merging seamless with governor collar 12, wherein shaft 11 has a diameter less than the diameter of governor collar 12, it is known that other configurations can be provided, wherein the diameter of the shaft 11 is equal to the diameter of collar 12 (not shown), and wherein a distinct seam may be provided between shaft 11 and governor collar 12 (not shown).

25 Figures 8, 8A and 9 contrast the fit of a prior art endodontic rotary file 22 within root canal 21 of tooth 20 with

that of rotary file 1 of this invention. For example, Figure 8 shows that prior art file 22 has annular space 23 between the top of the root canal and the active fluted region. This is a potential problematic area, which can lead to erratic engagement and eccentric movement of the fluted working surface of rotating endodontic file 22. An unguided lateral (non-centered) movement of endodontic file 22 can cause damage to the wall of tooth 20, possibly perforating tooth 20.

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Also, Figure 8A shows that the tip of file 22 will have

10 difficulty following the distal curvature of canal 21, and
therefore file 22 will tend to deviate sideways into the wall of
canal 21.

In contrast, according to the present invention shown in Figure 9, endodontic file 1 has a more conformal tight close fit to canal 21. Governor collar 3, being the widest part above the cutting region smoothly and closely contacts two points of the continuous inner wall of canal 21, which prevents cutting into the side of the top of root canal 21 as opposed to region 23 in Figure 8. Also, non-cutting tip 5 will more easily follow distal curvature by not cutting into the wall of canal 21.

The combination of governor collar 3 contacting the wall of canal 21 at two points, plus the contact of non cutting tip 5 at the apical end of canal 21, provides a three-point contact of non cutting surfaces of endodontic drill 1 with root canal 21, thereby minimizing the risk of damage to tooth 20 due to lateral non-centered movement of rotating endodontic file 1 against the

inner wall of canal 21 of tooth 20.

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Figures 10A, 10B and 10C show three different variations of shaft designs useful with any of the governor files of this invention. In addition, governor collars are short members wherein length L_g is typically 1.0 to 2.0 mm. Just as shaft diameter D_s is smaller than maximum active diameter D_h in Figure 1 to promote removal of debris from the root canal, the three shaft variations all have a diameter less than D_m which is the maximum diameter of the governor.

In Figure 10A, shaft diameter D_1 is only slightly smaller than D_m .

In Figure 10B, shaft diameter D_2 is significantly smaller than D_m (and therefore more flexible).

In Figure 10C, shaft diameter D_3 is similar to D_2 , but it increases to D_m more gradually.

Figure 11 shows an alternate embodiment using governor 53 which is comparable to governor 3 of Figure 2 with the exception that governor 53 is now a parallel (cylindrical) section instead of a tapered (conical) section as is governor 3.

Similarly, Figure 12 shows an alternate embodiment comparable to governor 12 in Figure 5 wherein tilted governor 62 is now a parallel (cylindrical) section instead of the tapered (conical) section as in governor 12.

Figure 13 shows a color and numerically coordinated visually ergonomic grouping of sets of three files, which are provided for each size canal of small, medium and large.

The overlapping inverted "Y" configuration of Figure 13 refers to the fact that files are either 21 or 25 mm in length. The left most inverted "Y" refers to the 21 mm length files and the right side inverted "Y" refers to the 25 mm length files. The three sets of overlapping inverted "Y"s refer to double sets of small, medium and large canal sizes in terms of width, wherein each set includes alternatively sets of files of 21 or 25 mm in length.

Figure 13 is actually a top plan view of a holder and organizer 70 for the endodontic files of this invention. It includes an annotated top sheet bonded to a substrate formed of a semi-rigid foam sponge block approximately 30 mm thick.

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Figure 13A is a front crossectional view of a portion of large file set 74 in holder and organizer 70, as depicted in ellipse "13A" of Figure 13.

The actual files are stored in the foam sponge block by driving the shafts through holes in the top sheet shown as dots in the three inverted "Y" displays marked "SMALL" set 72, "MEDIUM" set 73, and "LARGE" set 74. The millimeter scales 71 are used as a measuring convenience.

Figure 14 shows a typical set 80 of three files with indicia "A", "B" and "C". The reason for minimizing the number of files to sets of three files A, B and C for a respective root canal is because each root canal size needs only sequentially a first file A for first enlarging the root canal orifice, a second file B for cleaning most of the interior of the tapered root canal and a

third file C for finishing the shaping and last cleaning of the root canal.

The proximal tops 82, 84 and 86 of the files are identified with "A", "B" or "C".

The preferred taper of the initial file 81 is about .05 mm while the preferred length of the active region $L_{\rm e}$ is approximately 8mm.

The preferred taper for the second file 83 is about .04 mm while the length $L_{\rm n}$ of the active region is dependent on the tip as shown in the table in Figure 14, such as for example, between about 8 to 10 mm.

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The preferred taper of the third file 87 is about .06 mm while the length of the active region $L_{\rm f}$ is approximately 14 to 16 mm.

As further shown in Figure 14, endodontic files A, B and C are further color coordinated by slanted, aligned bands B_e, B_n and B_f at the proximal non-cutting cylindrical ends of the respective files 81, 83 and 87, wherein further the position of the respective band B_e, B_n or B_f upon the top, middle or lower portion of the proximal non-cutting cylindrical ends of the respective files 82 (A), 83 (B) or 87 (C) further defines the order of use of each file A, B or C to be used with a predetermined determination that the root canal is small, medium or large.

In the foregoing description, certain terms and visual depictions are used to illustrate the preferred embodiment.

However, no unnecessary limitations are to be construed by the terms used or illustrations depicted, beyond what is shown in the prior art, since the terms and illustrations are exemplary only, and are not meant to limit the scope of the present invention.

It is further known that other modifications may be made to the present invention, without departing the scope of the invention.